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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,242	09/12/2000	Timothy Myers	41118	6165

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/660,242	MYERS ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-44 and 56-65* is/are pending in the application.

4a) Of the above claim(s) *40-44,58,59 and 63-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39,56,57 and 60-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' election, with traverse, of Group 13 (claim 39), in Paper No. 12, filed 12/31/02, is acknowledged.

Applicants traversal is on the ground that claims 40-44 depend from claim 39, and therefore should be considered together with claim 39. This is not found persuasive because while the claims are dependent from claim 39, they are drawn to distinct subject matter as set forth in the previous Office action mailed 102/02. For instance, claim 39 is drawn to a method finding a drug target but claims 40-44 are drawn to drug targets or binding agent, which belong to different classes and are usually published separately in literature. Searching of these claims together would require different searching strategy and search different databases. Hence, it would impose undue search burden to the Office.

Thus, the restriction requirement is still deemed proper and thus made FINAL.

Applicants add new claims 56-65. Claim 58 is written as being dependent from claim 27, which is a non-elected invention. Claim 59 is written as being dependent from claim 58. Claim 63 is directed to a marker for diagnosis, etc., which is non-elected invention. Claims 64-65 are drawn to a binding agent, which is non-elected.

In summary, originally filed claims 40-44, newly added claims 58-59, and 63-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 39, 56-57, and 60-62 are currently under consideration.

Information Disclosure Statement

The Information Disclosure Statements in Papers #5 and #6, filed on 7/13/01 and 10/18/01, respectively, are received and references therein have been considered.

Drawings

At least one color photographs and/or color drawing has been found in the instant application (see Brief Description of the Drawings, page 6). Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Specification

The specification is objected to because of the following:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed. The title is directed to non-genetic protein disease markers whereas the elected invention is directed to methods for identifying a protein disease marker.

Blank is noted on page 39 after "U.S. serial number".

Appropriate correction is required.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 56-57, and 60-62 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "abnormal amount" in claim 39 is vague. Absent a clear definition in the specification, the standard of "abnormal amount" for a particular protein in a particular disease varies. The claim is thus indefinite.

The phrase "said disease state" in claim 39 lacks clear antecedent basis. It is not clear what disease state is meant.

The phrase "the individual" in claim 57 lacks clear antecedent basis. Plural "individuals" are referred to in claim 56, from which claim 57 depends. It is not clear what individual of the "individuals" is meant in claim 57.

Claim 56 is rejected due to its dependency from claim 39.

The phrase "the levels of each protein in said proteome" in claim 60 c) is vague and confusing. A particular protein in a particular proteome of a particular biological sample can only have one level. How can multiple levels be determined and compared?

The phrase "said markers" in claim 60 d) lacks clear antecedent basis. Only a singular "marker" is referred to in the preamble.

The phrase "the individual" in claim 62 lacks clear antecedent basis. Plural "individuals" are referred to in claim 61, from which claim 62 depends. It is not clear what individual of the "individuals" is meant in claim 62.

Claim 61 is rejected due to its dependency from claim 60.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b) that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 56, and 60-61 are rejected under 35 U.S.C. § 102(b) as being anticipated by Pleibner et al. (Electrophoresis, 1998, Vol. 19, pages 2043-2050).

Claims 39, 56, and 60-61 are drawn to methods of identifying proteins that can be markers for diseases of obesity, osteopporosis, diabetes, osteoarthritis or hypertension.

Pleibner et al. disclose a method of identifying protein markers of hypertensive heart disease caused by renovascular hypertension through establishing myocardial protein patterns from a group of hypertensive and control rats and comparing the patterns by computer-assisted two-dimensional (2-D) gel electrophoresis and analysis including univariate and multivariate statistical approaches. See abstract on page 2043 and page 2044, left column. Total proteins, i.e.

proteome, of tissue samples are separated and the level of individual protein separated is measured through 2-D gel analysis assisted with computer analysis. See page 2044, left column, page 2045, left column. Of multiple proteins, 4 proteins were identified to be clearly different, and one protein statistically different, between hypertensive and control samples. See page 2045, left column and Table 2 on page 2047. The method of Pleibner et al. also attempts to determine whether the difference of protein levels detected agrees with the previously detected difference including a database of human heart proteins. The spot with a significant decrease in the hypertensive group is located near the creatine kinase M-chain, which was previously detected to exhibit changes in hypertensive models. See page 2049, left column. Thus, this protein detected by Pleibner et al. is likely in the same pathway of the disease stage, i.e. early stage of hypertension.

In regard to claims 56 and 61 which require that the biological sample and control sample be from genetically identical individuals, the method of Pleibner et al. uses Glodblatt 2K-1C to induce hypertension of Wistar-Kyoto rats and uses un-induced group as control. See page 2044, left column, section 2.1. Since the Glodblatt 2K-1C would not induce any genetic changes, the two groups would be genetically identical.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pleibner et al. (Electrophoresis, 1998, Vol. 19, pages 2043-2050) as applied to claims 39, 56, 60-61 above, and further in view of Chambers et al. (Journal of Pathology, 2000, Vol. 192, pages 280-288).

As set forth above, Pleibner et al. disclose a method for identifying markers for rat hypertension disease. Pleibner et al. do not explicitly disclose using human biological samples. However, since it would have been well known that rat would be one of the most commonly used models for studying human diseases, one of ordinary skill in the art would have been motivated to modify Pleibner et al. to study human hypertension disease using the same computer assisted two-dimensional electrophoresis.

Furthermore, Chambers et al. reviews the application of proteomics in studying diseases including human diseases. See page 280, Abstract. Chambers et al. also suggest that the application of proteomics privides major opportunities to elucidate disease mechanisms and to identify new diagnostic markers and therapeutic targets. Thus, one of ordinary skill in the art would have been motivated by Chambers et al. to modify Pleibner et al. to study human diseases including hypertension. There would have been reasonable expectation of success because Pleibner et al. and Chambers et al. describe the details of the methods.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

Patent Examiner

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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